Bio (Overweight)

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Industry Report

Stem cells: At the heart of the bio industry

- Hearticellgram-AMI: A bone marrow-derived stem cell therapy
- World's first approval of stem cell drug warrants revaluation of autologous stem cell companies
- Focus on RNL Bio and FCB Twelve (autologous stem cell companies) and Medipost (thanks to Cartistem)

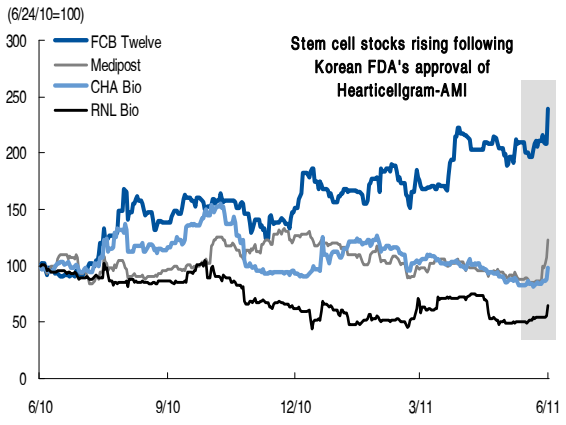
■ The world's first approval for a stem cell treatment seems imminent

On June 24th, it was reported that the Korean FDA is highly likely to approve Hearticellgram-AMI, a stem cell therapy developed by FCB-Pharmicell. This would mark the first approval of a stem cell treatment in history. Since the news broke, shares related to stem cell companies—including FCB Twelve (a parent company of FCB-Pharmicell), RNL Bio, and Medipost—have skyrocketed. This development is also forcing investors to pay greater attention to the bio industry in general. It seems that stem cells are now at the heart of the bio industry.

■ Hearticellgram-AMI

Hearticellgram-AMI is a stem cell treatment for acute myocardial infarction, derived from the patient's own bone marrow. The drug is made from mesenchymal stem cells (contained in bone marrow) which are separated and cultured for three to four weeks. The Hearticellgram-AMI is then injected directly into the patient's heart. According to FCB Twelve's Phase 3 clinical trial, patients who had underwent a cardiac angioplasty showed a 6% higher left ventiricular ejection fraction (LVEF), six months after being injected with Hearticellgram-AMI.

Figure 1. Price trends of major domestic stem cell companies



Source: Daewoo Securities Research

Figure 2. Hearticellgram-AMI

Source: FCB Twelve

■ What would approval for a stem cell treatment mean?

1) Approval would confirm stem cells' potential for treating diseases that have been resistant to existing medical technologies and synthetic drugs.

2) Hearticellgram-AMI uses mesenchymal stem cells extracted from patients' own bone marrow. As a result, the therapy's toxicity levels are low, which should increase its commercial potential. Indeed, the use of patients' own tissues should grab greater attention.

3) Approval would likely expedite the legislative process of a National Assembly bill proposing a simplified clinical trial for stem cell therapies using patients' own tissues. The bill, which is still pending at the Health and Welfare Committee, is likely to receive a positive response.

■ Is a 6% higher LVEF good enough?

Some argue that a mere 6% increase in LVEF is disappointing given that the treatment is estimated to cost over W20mn. However, we believe the treatment is meaningful for the following reasons:

(1) Overcoming current limitations: Although a 6% improvement may be lower than expected, we find the treatment to be significant as it can overcome the limitations of current medical technology and synthetic drugs. Patients who have had heart surgery are keen to improve their LVEF, albeit slightly.

(2) Potential for further LVEF improvement: While the treatment is currently based on a single dose injection, a variety of other treatment procedures can be developed, making room for further LVEF improvement.

■ Keep an eye on potential risks

FCB-Pharmicell is expected to aim to attract 10% of Korea's myocardial infarction patients (currently around 65,000 per year) in the mid- to long-term. Although initial sales of Hearticellgram-AMI will not be covered by the national health insurance, the company is likely to attempt to add the treatment to the insurance coverage list. However, investors should keep an eye on the company's strategy and performance in light of potential risks, including: 1) the possibility that Hearticellgram-AMI's market share may only be 2~3%, 2) the company's potential failure to gain coverage for the therapy, and 3) marketing difficulties.

■ Focus on providers of autologous stem cell therapies

Autologous stem cell therapies (i.e. stem cells derived from patients' own bodies) are likely to draw keen attention, in light of: 1) their low toxicity levels and 2) favorable regulatory measures. Korea's major stem cell companies are RNL Bio (003190 KS), which focuses on adipose-derived stem cells, and FCB Twelve (005690 KS), which is likely to receive approval soon for its bone marrow-derived stem cell therapy.

Attention to Medipost (078160 KQ) should also remain steady, as the company is pushing to get approval for Cartistem, a rheumatoid arthritis treatment using human umbilical cord blood-derived stem cells. We expect this treatment to be approved in 2H11.

Table 1. Clinical trial status for treatments of major domestic stem cell companies

Company	Type of stem cell	Product name	Symptoms	Administration	Mechanism	Domestic development process	Expected domestic release
FCB-Pharmicell	Adult (autologous, bone marrow)	Hearticellgram-AMI	Myocardial infarction	Surgery	Heart cell regeneration	Approval	2011
FCB-Pharmicell	Adult (autologous, bone marrow)	MSC1	Acute cerebral infraction	Intravenous	Cerebral cell regeneration	Phase 3	2013
RNL Bio	Adult (autologous, adipose)	Vascostem	Buerger's disease	Intravenous	Blood vessel regeneration	Phase 2	2013
RNL Bio	Adult (autologous, adipose)	RNL-Jointstem	Osteoarthritis	Injection	Cartilage regeneration	Phase 1/2	2013
Medipost	Adult (allogeneic, cord blood)	Cartistem	Osteoarthritis	Surgery	Cartilage regeneration	Evaluation	2012

Source: Company data

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